



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Walter Newman

Application No.: 10/717,984

Group Art Unit: 1644

Filed: November 20, 2003

Examiner: Maher M. Huddad Ph.D.

Confirmation No.: 8906

Title: HMGB1 COMBINATION THERAPIES

CERTIFICATE OF MAILING OR TRANSMISSION	
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<u>May 8 2006</u>	<u>Christine A. Budd</u>
Date	Signature
CHRISTINE A. BUDD	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

05/11/2006 FFANAEIA 00000060 10717984

Sir:
01 FC:1806

180.00 OP

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☒ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☒ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

☒ Enclosed herewith is form PTO-1449:

☒ Copies of the cited references [B1-B9 and C1-C83] are enclosed.

☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

☒ The listed references C1-3 were cited in the enclosed International Search Report and references B1 and C4-7 were cited in the enclosed Supplementary Partial European Search Report in counterpart foreign applications.

☒ The "concise explanation" requirement (non-English references) for reference(s) B6 and B9 under 37 CFR 1.98(a)(3) is satisfied by:

☐ the explanation provided on the attached sheet.

☐ the explanation provided in the Specification.

☐ submission of the enclosed International Search Report.

☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

☒ the enclosed English language abstract.

☒ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 10/147,447, by Kevin J. Tracey, *et al.*, filed May 15, 2002,
Docket No.: 3268.1001-001

____ U.S. Patent Application No. 10/300,072, by Kevin J. Tracey, *et al.*, filed November 20,
2002, Docket No.: 3268.1001-005 and current claims.

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

☒ A copy of each above-cited application, including the current claims, is enclosed.

☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

☒ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated: May 8, 2006

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
3258.1008-001APPLICATION NO.
10/717,984INFORMATION DISCLOSURE CITATION
IN AN APPLICATIONFIRST NAMED INVENTOR
Walter NewmanFILING DATE
November 20, 2003

May 8, 2006

EXAMINER
Maher M. Huddad Ph.D.CONFIRMATION NO.
8906GROUP
1644

(See several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	A1	5,594,114	01/14/1997	Goodearl, A. D. J., <i>et al.</i>
	A2	6,303,321 B1	10/16/2001	Tracey, K. J.
	A3	6,448,223 B1	09/10/2002	Tracey, K. J. and Wang, H.
	A4	6,468,533 B1	10/22/2002	Tracey, K. J. and Wang, H.
	A5	2003/0060410 A1	03/27/2003	Tracey, K. J., <i>et al.</i>
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	A10	6,720,472 B2	04/13/2004	Chada, K.K., <i>et al.</i>
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EXAMINER

DATE CONSIDERED

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION May 8, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3258.1008-001		APPLICATION NO. 10/717,984	
	FIRST NAMED INVENTOR Walter Newman		FILING DATE November 20, 2003	
	EXAMINER Maher M. Huddad Ph.D.	CONFIRMATION NO. 8906	GROUP 1644	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1	EP 1 033 401 A2	09/06/2000	GENSET		
	B2	WO 00/47104 A2	08/17/2000	The Picower Institute for Medical Research		
	B3	WO 99/59609 A2	11/25/1999	Bartorelli, A.		
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	B6	WO 2004/004763 A2	01/15/2004	Bianchi, M. E., <i>et al.</i>		
	B6	JP 62-166897	07/23/1987	Toyo Soda Mfg Co. Ltd., <i>et al.</i>		X
	B7	EP 1 079 849 B1	01/02/2002	Bartorelli, A.		
	B8	WO 96/25493 A1	08/22/1996	K.U. Leuven Research & Development		
	B6	WO 97/23611 A2	07/03/1997	Bullerdiek, J.		X
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C1	Wang, H., <i>et al.</i> , "HMG-1 as a Late Mediator of Endotoxin Lethality in Mice," <i>Science</i> , 285:248-251 (1999).	
C2	Andersson, U., <i>et al.</i> , "High Mobility Group 1 Protein (HMG-1) Stimulates Proinflammatory Cytokine Synthesis in Human Monocytes," <i>J. Exp. Med.</i> , 192(4):565-570 (2000).	
C3	Abraham, E., <i>et al.</i> , "Cutting Edge: HMG-1 as a Mediator of Acute Lung Inflammation," <i>J. Immunol.</i> , 165:2950-2954 (2000).	
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C5	Geneseq Accession No. AAG03823, "Human secreted protein, SEQ ID No: 7904," (2000) [online] [retrieved on 03/21/2006]. Retrieved from the Internet (incomplete URL provided on copy).	
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C9	Ayer, L. M., <i>et al.</i> , "Antibodies to HMG Proteins in Patients With Drug-Induced Autoimmunity," <i>Arthritis Rheum.</i> , 37(1):98-103 (1994).	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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C16	Bustin, M., "Revised Nomenclature for High Mobility Group (HMG) Chromosomal Proteins," <i>Trends Biochem. Sci.</i> , 26:152-153 (2001).
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C18	Colman, P. M., "Effects of Amino Acid Sequence Changes on Antibody-Antigen Interactions," <i>Res. Immunol.</i> , 145(1):33-36 (1994).
C19	Czura, C., <i>et al.</i> , "Dual Roles for HMGB1: DNA Binding and Cytokine," <i>J. Endotoxin Res.</i> , 7(4):315-321 (2001).
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C22	Falciola, L., <i>et al.</i> , "High Mobility Group 1 Protein is Not Stably Associated with the Chromosomes of Somatic Cells," <i>J. Cell. Biol.</i> , 137(1):19-26 (1997).

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C23	Freeman, B. D., <i>et al.</i> , "The Role of Inflammation in Sepsis and Septic Shock: A Meta-Analysis of Both Clinical and Preclinical Trials of Anti-Inflammatory Therapies," in <i>Inflammation: Basic Principles and Clinical Correlates</i> (John I. Gallin and Ralph Snyderman eds., Lippincott, Williams & Wilkins, Philadelphia, 3 rd ed.), pp 965-975 (1999).
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C26	Johns, E. W., <i>et al.</i> , "History, Definitions and Problems," in <i>The HMG Chromosomal Proteins</i> , (London: Academic Press), pp. 1-7 (1982).
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C33	Merenmies, J., <i>et al.</i> , "30-kDa Heparin-Binding Protein of Brain (Amphoterin) Involved in Neurite Outgrowth," <i>J. Biol. Chem.</i> , 266(25):16722-16729 (1991).
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C36	Mohan, P. S., <i>et al.</i> , "Sulfoglycolipids Bind to Adhesive Protein Amphoterin (p30) in the Nervous System," <i>Biochem. Biophys. Res. Commun.</i> , 182(2):689-696 (1992).
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C37	Parkkinen, J., <i>et al.</i> , "Amphoterin, the 30-kDa Protein in a Family of HMG1-type Polypeptides," <i>J. Biol. Chem.</i> , 268(26):19726-19738 (1993).
C38	Passalacqua, M., <i>et al.</i> , "Stimulated Astrocytes Release High-Mobility Group 1 Protein, an Inducer of Lan-5 Neuroblastoma Cell Differentiation," <i>Neuroscience</i> , 82(4):1021-1028 (1998).
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C40	Rauvala, H., <i>et al.</i> , "The Adhesive and Neurite-Promoting Molecule p30: Analysis of the Amino-Terminal Sequence and Production of Anti-peptide Antibodies That Detect p30 at the Surface of Neuroblastoma Cells and of Brain Neurons," <i>J. Cell Biol.</i> , 107(6):2293-2305 (1988).
C38	Romani, M., <i>et al.</i> , "Serological Analysis of Species Specificity in the High Mobility Group Chromosomal Proteins," <i>J. Biol. Chem.</i> , 254(8):2918-2922 (1979).
C42	Salmivirta, M., <i>et al.</i> , "Neurite Growth-Promoting Protein (Amphoterin, p30) Binds Syndecan," <i>Exp. Cell Res.</i> , 200:444-451 (1992).
C43	Scaffidi, P., <i>et al.</i> , "Release of Chromatin Protein HMGB1 by Necrotic Cells Triggers Inflammation," <i>Nature</i> , 418:191-195 (2002).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C44	Sobajima, J., <i>et al.</i> , "Prevalence and Characterization of Perinuclear Anti-Neutrophil Cytoplasmic Antibodies (P-ANCA) Directed Against HMG1 and HMG2 in Ulcerative Colitis (UC)," <i>Clin. Exp. Immunol.</i> , 111:402-407 (1998).
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C50	Tsuneoka, M., <i>et al.</i> , "Monoclonal Antibody Against Non-Histone Chromosomal Protein High Mobility Group 1 Co-Migrates With High Mobility Group 1 Into the Nucleus," <i>J. Biol. Chem.</i> , 261(4):1829-1834 (1986).
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C52	Vanderbilt, J. N. and Anderson, J. N., "Monoclonal Antibodies as Probes for the Complexity, Phylogeny, and Chromatin Distribution of High Mobility Group Chromosomal Proteins 1 and 2," <i>J. Biol. Chem.</i> , 260(16):9336-9345 (1985).
C53	Wang, H., <i>et al.</i> , "Proinflammatory Cytokines (Tumor Necrosis Factor and Interleukin 1) Stimulate Release of High Mobility Group Protein-1 by Pituicytes," <i>Surgery</i> , 126(2):389-392(1999).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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C60	Yamada, S., <i>et al.</i> , "High Mobility Group Protein 1 (HMGB1) Quantified by ELISA with a Monoclonal Antibody That Does Not Cross-React with HMGB2," <i>Clin. Chem.</i> , 49(9):1535-1537 (2003).
C56	Zhang, M and Tracey, K. J., "Tumor Necrosis Factor," in <i>The Cytokine Handbook</i> , (Academic Press Limited), Third Edition, pp. 517-548 (1998).
C57	GenBank Accession No. AC010149, "Homo sapiens BAC clone RP11-395A23 from 2, complete sequence," (2001) [online] [retrieved on 4/18/2006]. Retrieved from the Internet: <URL:http://www.ncbi.nlm.nih.gov>.
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION May 8, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3258.1008-001		APPLICATION NO. 10/717,984	
	FIRST NAMED INVENTOR Walter Newman		FILING DATE November 20, 2003	
	EXAMINER Maher M. Huddad Ph.D.	CONFIRMATION NO. 8906	GROUP 1644	

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